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10/561,540

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EXAMINER

ANDERSON, DENISE R

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/561,540 | Applicant(s) DA SILVA GONCALVES ET AL. | |
| | Examiner Denise R. Anderson | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12 and 13 is/are rejected.
- 7) ☒ Claim(s) 1, 3 and 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>19 December 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informality: a "NF membrane" is recited and one of ordinary skill in the art might not realize that an NF membrane is a nanofiltration membrane. Appropriate correction is required.
2. Claim 3 is objected to because of the following informality: In line 2, claim 3 recites "ionic species can be total or partial removed" and should read "ionic species can be totally or partially removed." Appropriate correction is required.
3. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim recites the process is carried out in "a continuous or a batch mode." Since there are no other options other than a continuous or a batch mode, claim 8 fails to further limit claim 1 upon which it depends.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Claim 1, part c, recites "distilling the retentate . . . leading to a top stream rich in ethanol and a bottom stream of dealcoholized permeate." The drawing shows the permeate stream 8 being distilled and not the retentate stream 7 as recited in the claim. The specification recites claim 1 exactly, in paragraphs 9-16. In the patentability analysis below, the examiner will interpret the claim to be in line with the drawing.

6. Claims 1-10 are rejected a second time under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites nanofiltration membranes and the specification states, in paragraph 7, that nanofiltration membranes are different from reverse osmosis membranes but does not state what the difference is such that one of ordinary skill in the art would know whether the membrane in question is an infringing nanofiltration membrane or a non-infringing reverse osmosis membrane. As the MPEP states at 2173.02, "If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate. See *Morton Int 'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993)."

7. In the patentability analysis below, it will be shown that Lee et al. anticipates the recited process. Lee et al. teaches the membrane characteristics and membrane materials that will work in that process. As such, the examiner interprets applicant's nanofiltration membrane to be disclosed by Lee et al.. Specifically, Lee et al. teaches

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membrane characteristics when it is stated, "Membranes that are now used for reverse osmosis (RO) are good candidates for use in this invention, because RO applications entail high transmembrane water fluxes of polar permeants (e.g., water). Membranes that permit rapid water permeation usually will be significantly permeable to ethanol as well. Membranes which exhibit ethanol and/or water fluxes adequate for the present invention should be thin, nonporous, and may be derived from polymers that are crosslinked or uncrosslinked, glassy or rubbery, and water-swollen to various degrees." Lee et al., Column 32, lines 47-52. Note that the "polar permeates" would include salts, as well as water and ethanol. Furthermore, a polymeric membrane that is uncross-linked, rubbery, and water-swollen would facilitate salt transfer, as well as water and ethanol transfer.

8. Lee et al. further teaches materials for the membranes at Column 33, lines 41-52 when Lee et al. states, "In view of the above considerations, a number of membrane types may be useful for the selective removal of ethanol from alcoholic beverages including, but not limited to, various aliphatic and aromatic polyamides, polyureas, polyetherureas, polyimides, polyoxazolines, polyetheraminotriazine, regenerated cellulose, cellulose acetate, cellulose triacetate, crosslinked polyvinyl alcohol, polyacrylonitrile and its copolymers (these polymers being particularly resistant to ethanol swelling), polybenzimidazole, and polybenzimidazolone, hydrophilic crosslinked vinyl polymers and copolymers, and ion-exchange membranes with various counter ions."

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9. In summary, Lee et al. will be shown to anticipate the claimed process in the patentability analysis, below. Regarding that process, Lee et al. further teaches membrane characteristics and materials that would allow one of ordinary skill in the art to determine if a given membrane would work. As such, Lee et al. discloses the claimed, but undefined, nanofiltration membrane.

10. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "long" in the phrase "long time" recited in claim 7 is a relative term which renders the claim indefinite. The length of "time" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the patentability analysis below, the examiner will interpret claim 7 to recite that any amount of time is a "long" time.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 2, 8, 10, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (US Patent No. 5,013,447, May 7, 1991).

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13. The patentability analysis will begin with claim 1. In Figures 6, 12, and 18, Lee et al. discloses a method "for manipulating the ethanol content in alcoholic beverages by selectively removing . . . water and ethanol in any desired proportion" while "minor components that contribute to the flavor and aroma of the beverages are substantially retained in the product beverage" but not totally retained. Lee et al., Column 10, lines 50-56. This is analogous to the recited process for the reduction of alcohol content of beverages.

14. Lee further discloses, "The present invention, in a specific embodiment, relates to a method comprising exposing one side of a membrane to a beverage and the other side of the membrane to a gas-phase extraction fluid, and equalizing the water activities in the beverage and throughout the gas-phase by adjusting the amount, pressure or temperature of the water vapor in the gas-phase extraction fluid. The process of this invention is referred to as vapor-arbitrated pervaporation." Lee et al., Column 11, lines 24-32.

15. Regarding the pervaporation process, Lee et al. refers to Figure 6 and teaches, "A membrane unit comprises two flow compartments, one on each side of the membrane 15. Beverage 10 is fed to compartment A of the membrane unit, a gas-phase extraction fluid 31 comprising a mixture of non-condensable gas (such as air or nitrogen) and water vapor is fed to the other compartment B as a sweep stream. . . . The beverage emerges with a reduced alcoholic content 16. An alcohol recovery subsystem 39 separates the water and ethanol 40 from the non-condensable gas 37 in the gas-phase extraction fluid that emerges 32." Lee further teaches, "Membranes that

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are now used for reverse osmosis (RO) are good candidates for use in this invention."

Lee et al., Column 32, lines 47-48. As was discussed in the 112 rejections, these reverse osmosis membranes are interpreted to be the nanofiltration membranes recited in claim 1. Lee et al. discloses that, for examples 1 and 2, "The membrane module is of a plate-and-frame modular construction." Lee et al., Column 34, lines 22-24. In other words, the flow is tangential across the face of the membrane. Lee et al. continues, "The alcoholic beverage may be processed at or near atmospheric pressure." Lee et al., Column 21, lines 20-21. This is less than the recited maximum 40 bar recited in claim 1, limitation (a). To recap, Lee et al. discloses circulating the beverage from a feed tank, pressurized at a maximum 40 bar, tangentially across a nanofiltration membrane, to obtain a retentate stream and a permeate stream, as recited in claim 1, limitation (a).

16. In Figure 18, Lee et al. discloses circulating the beverage from the feed tank (feed liquid) to the nanofiltration membrane (membrane), across the nanofiltration membrane tangentially, and then returning the retentate stream to the feed tank. In other words, Lee et al. discloses claim 1, limitation (b), which recites the retentate is combined with the beverage to be processed in the feed tank.

17. In Figure 12, Lee et al. discloses that the alcohol recovery subsystem 39 includes a still 59 (applicant's distillation unit 9). Lee further et al. teaches, "The alcoholic beverage may be processed at or near atmospheric pressure." Lee et al., Column 21, lines 20-21. This is the atmospheric or reduced pressure recited for the distilling step in claim 1, limitation (c). To recap, Lee et al. discloses the permeate stream (water and

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ethanol liquid stream 40) is distilled, at atmospheric or reduced pressure, into a top stream (ethanol vapor 57) rich in ethanol and a bottom stream (liquid water 37') of dealcoholized permeate, as recited in claim 1, limitation (c).

18. Lee et al. discloses that the dealcoholized permeate (water stream from applicant's distillation unit 9) is recombined with the retentate / beverage when Lee et al. teaches, for a hybrid reverse osmosis distillation process for alcohol reduction, "Permeate generated by reverse osmosis treatment of feed wine was vacuumed distilled to separate ethanol from the water, which was recycled back to the feed beverage." Lee et al., Column 5, lines 59-63. As such, Lee et al. discloses claim 1, limitation (d).

19. Lee et al. further teaches that "when exchanging part or most of the native water contained in the beverage . . . the water used for pre-dilution or reconstitution must be thoroughly purified so as to minimize introduction of foreign materials into the beverage." Lee et al., Column 4, lines 64-65 and Column 5, lines 8-10. As such, Lee et al. discloses adding purified water to totally or partially compensating for volume loss due to ethanol removal, as recited in claim 1, limitation (e).

20. In summary, Lee et al. anticipates independent claim 1.

21. The patentability analyses for dependent claims 2, 8, 10, 12, and 13 follow. Regarding claim 2, Lee et al. further discloses that the membrane is "derived from polymers that are crosslinked or uncrosslinked, glassy or rubbery, and water-swollen to various degrees." Lee et al., Column 32, lines 55-57. An uncrosslinked, rubbery, water-

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swollen polymeric membrane is adjusted to facilitate transfer of salts, as recited. In summary, Lee et al. anticipates claim 2.

22. As was stated above in the claim objections, claim 8 fails to further limit claim 1 upon which it depends. Therefore, Lee et al. anticipates claim 8.

23. Regarding claims 10 and 13, Lee et al. further discloses that the final product presents the same organoleptic characteristic of the original beverage [claim 10] when Lee et al. teaches, "The alcohol-reduced samples retain virtually all of the flavor and bouquet of the original wine." Lee et al., Column 34, lines 52-53. Lee et al. further teaches that the recited organoleptic characteristic include body, flavour, and aroma (aroma intensity and aromatic profile) [claim 13] when Lee et al. states, "In each case, ingredients some of which are volatile, that contribute to the flavor, aroma, body and even color of the starting liquid are substantially retained in the product liquid or beverage." Lee et al., Column 2, lines 2-6.

24. Regarding claim 12, Lee et al. further discloses that the beverage "is selected from the group consisting of wine, sparkling wine, whisky, brandy, sake, beer or a fermented fruit drink." Lee et al., Column 42, lines 14-16. This anticipates applicant's recited wine, beer, cider, and sake.

25. In summary, Lee et al. anticipates dependent claims 2, 8, 10, 12, and 13.

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

27. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

28. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

29. Claims 3, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US Patent No. 5,013,447, May 7, 1991) as applied to claim 1 above.

30. Lee et al. discloses the claimed invention and implies that ionic species are removed from the water produced by the distilling step (the recited dealcoholized permeate) when the beverage is reconstituted with native water. Specifically, Lee et al. teaches that "when exchanging part or most of the native water contained in the

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beverage . . . the water used for pre-dilution or reconstitution must be thoroughly purified.” Lee et al., Column 4, lines 64-65 and Column 5, lines 8-10. This purification would include removing ionic species from the water produced by the distilling step (the dealcoholized permeate), as recited in claim 3. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have removed the ionic species in the Lee et al. water from the distillation step (applicant’s dealcoholized permeate) since it was known in the art that “when exchanging part or most of the native water contained in the beverage . . . the water used for pre-dilution or reconstitution must be thoroughly purified.” Lee et al., Column 4, lines 64-65 and Column 5, lines 8-10.

31. Regarding claim 9, Lee et al. discloses the claimed invention except for explicitly teaching blending the original beverage with the processed beverage. However, Lee et al. further teaches that such blending is known in the art when Lee et al. discloses, “For example, Dziondziak, in U.S. Pat. No. 4,814,188, produced low-alcohol beer by conducting fermentation with an alcohol dehydrogenase-negative yeast mutant incapable of forming ethanol but capable of forming glycerol, then blended the product with normally produced beer,” for the purpose of “controlling the ethanol content.” Lee et al., Column 3, lines 18-23 and 1-2. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have blended the original beverage with the processed beverage since it was known in the fermented beverage art to do this for the purpose of “controlling the ethanol content.” Lee et al., Column 3, lines 18-23 and 1-2.

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32. Regarding claim 12, Lee et al. discloses the claimed invention except for explicitly teaching the mead beverage, which is a fermented honey and water beverage. Lee et al. teaches a method for “reducing the volume of an alcoholic beverage comprising at least two volatile solvents including an alcohol and water in which substantially any predetermined desired concentrations of alcohol and water in an alcoholic beverage is provided, while preserving the flavor and aroma of the alcoholic beverage.” Lee et al. further teaches that such a method can be used for fermented beverages such as “wine, sparkling wine, whisky, brandy, sake, beer or a fermented fruit drink.” It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the Lee et al. method to reduce the alcoholic content of mead because of the equivalence of mead to the fermented beverages of wine, beer, sake, and hard cider for their use as a fermented beverage feedstock in the ethanol reduction art and the selection of any of these known equivalents for ethanol reduction would be within the level of ordinary skill in the art.

33. In summary, Lee et al. discloses or suggests all limitations recited in claims 3, 9, and 12.

34. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US Patent No. 5,013,447, May 7, 1991) as applied to claim 1 above, and further in view of Galzy et al. (US. Patent No. 4,610,887, Sep. 9, 1986).

35. Lee et al. discloses the claimed invention except for the circulation of water at room temperature. Galzy et al. teaches that this is known in the context of “a process

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for treating fermented juices by reverse osmosis.” Galzy et al., Abstract, lines 2-3.

Specifically, Galzy et al. discloses “a planar reversed osmosis module” that is operated at 26°C where membrane plugging is prevented by submitting the membrane “to a washing about every 24 hours.” Galzy et al. Column 9, lines 6 and 10-11. Galzy et al. further teaches, “The washing consists of passing over the membrane slightly acidified water for 15 to 20 minutes at ambient pressure and at 60 bars, then rinsing the module with water.” Galzy et al., Column 9, lines 14-19. In Table 3, Galzy et al. discloses running the process for 70 hours in the last column on the right. As such, Galzy et al. discloses maintaining the membrane flux over a period of days by washing the membrane with water at room temperature once every 24 hours. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have circulated water at room temperature in the Lee et al. process as taught by Galzy et al., since Galzy et al. states at Column 9, line 14 that such a modification would be useful “to prevent plugging up of the membrane.”

36. Lee, in view of Galzy et al., discloses or suggests all claim 4 limitations except for stating explicitly that the transmembrane flux was 90%. Galzy et al. teaches maintaining the membrane flux over a period of days by washing the membrane with water at room temperature once every 24 hours. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have regenerated the membrane to at least 90% flux recovery, since it has been held that where the general conditions of a claim are disclosed in the prior art (regenerating the membrane once daily for a period of days), discovering the optimum or workable ranges

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(regenerating the membrane to 90% flux recovery) involves only routine skill in the art.

In re Aller, 105 USPQ 233.

37. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US Patent No. 5,013,447, May 7, 1991) as applied to claim 1 above, in view of Galzy et al. (US. Patent No. 4,610,887, Sep. 9, 1986) for circulation of water at room temperature to clean the membrane, and further in view of Gan et al. (*J. of Membrane Science* 155 (1999) 277-289) for increasing the cleaning temperature, adding cleaning agents to the water, and controlling the pH.

38. As shown in the claim 4 patentability analysis, Lee et al., in view of Galzy et al. discloses the method with a cleaning procedure of circulating water at room temperature. In the context of beer filtration, Gan et al. discloses cleaning membranes "within the applied chemical cleaning temperature range of 20-80°C and pH 1-13.5." Gan et al., Title; p. 279, § 2.1, ¶ 1, lines 6-7. In Fig. 1 on p. 279, Gan et al. further teaches computer control of the process. Gan et al. disclosed that "the complete cleaning time, t_c , varied with cleaning chemicals" and that "[e]xtended cleaning beyond t_c had minimal effect and should be avoided for economic considerations and longer membrane life." Gat et al., p. 282, § 3.2.1, ¶ 1, lines 3-6. As such, Gan et al. discloses a water circulation temperature of between 50-60°C [claim 5], aqueous solutions of weak bases with pH control between 8 and 11 as a function of cleaning time [claim 6], and a cleaning solution of pH between 8 and 9 [claim 7]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have included,

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in the Lee et al. process, the cleaning cycle limitations recited in claims 5-7, as taught by Gan et al., since Gan et al. states in the Title, that such modifications would be useful for cleaning membranes in a beer filtration process.

Conclusion

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Denise R. Anderson whose telephone number is (571)270-3166. The examiner can normally be reached on Monday through Thursday, from 8:00 am to 6:00 pm.

40. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter D. Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

41. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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DRA

/Walter D. Griffin/

Supervisory Patent Examiner, Art Unit 1797